

### Remarks

After amendment, claims 20-24, 27-34 and 37-39 remain pending in the present application. Support for the amendment to the claims may be found throughout the originally filed application, examples and claims and in particular, *inter alia* on page 5, lines 17-27, page 10, lines 6-16, page 11, lines 19-27, page 13, lines 4-25, page 14, page 15, and page 19 of the specification. No new matter has been added by way of the present invention. The amendment to the claims has been made to address the Examiner's double patenting rejection and to further provide dependent and independent claims directed to the claimed invention. Applicants note that they have cancelled subject matter *without prejudice* which is directed to the issue of enablement. Applicants note that such subject matter is enabled; nonetheless, rather than present evidence in support of that enablement, Applicants wish to expedite allowance of the instant application and present the enablement evidence, if required, in a subsequent divisional application.

Applicants note a request from the Examiner to provide copies of the references cited in the originally filed information disclosure statement, noting the fact that the original references submitted in the parent application are unavailable to the Examiner. Applicants have submitted those references several weeks ago under separate cover.

The Examiner has objected to the specification and/or rejected the present invention variously under 35 U.S.C. §101, the judicially created doctrine of obviousness-type double patenting and under 35 U.S.C. §112, first paragraph for the reasons which are stated in the office action on pages 2-18. Applicants shall address each of the objections/rejections in the sections which follow.

### The Objection to the Specification

The Examiner has objected to the specification for the reasons which are set forth in the office action on page 2. In response, Applicants have amended the second paragraph on page 9, in line 12, as suggested by the Examiner.

### The Rejection of the Application Under 35 U.S.C. §112, First Paragraph

The Examiner has rejected the instant invention under 35 U.S.C. §112, first paragraph as being non-enabling for the treatment of cancers for the reasons which are set forth in the office action on page using the compounds which are claimed. The Examiner posits that the specification does not provide enablement for head and neck, bladder, uterine and small cell lung cancer and other cancers where R<sup>1</sup> and R<sup>2</sup> of the claimed nucleoside compound are other than H.

The Examiner bases the rejection on generally accepted principles of pharmaceutical practice as applied to the instant case. Applicants believe that the Examiner has not made out a credible case that the originally filed claims are not enabled. Applicants believe that the previously filed claims directed to the invention are enabled, that the data set forth in the specification is predictive of enablement for various forms of cancer as claimed, and that the claimed compounds, which represent *prodrug* forms of the underlying nucleoside analog are clearly enabled and useful for treating a broad spectrum of cancers. Nonetheless, in order to expedite allowance of the instant application, Applicants have cancelled certain subject matter from the originally filed claims *without prejudice* and will proceed to address any issues of patentability, if required, in a subsequent divisional application.

It is respectfully submitted that the presently claimed invention is in compliance with the requirements of 35 U.S.C. §112, first paragraph.

The Rejection under 35 U.S.C. §101 or the Judicially Created Doctrine of Obviousness-  
Type Double Patenting

The Examiner has rejected several of the previously filed claims (21-23 and 29) under 35 U.S.C. §101 as claiming the same subject matter as claims 1, 3-6 and 9-15 of United States patent number 5,817,667 ("the '667 patent") constituting a double patenting rejection. Inasmuch as claims 21-23 and 29 have been amended to reflect a change in scope from previously presented claims, it is respectfully submitted that Applicants have obviated the Examiner's rejection on these grounds. The Examiner is respectfully requested to withdraw his rejection of the instant application in light of the amendment to the claims.

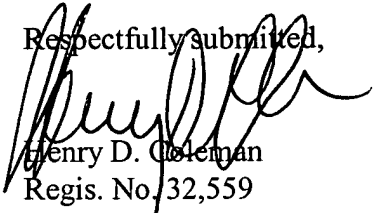
Regarding the Examiner's obviousness-type double patenting rejection of a number of claims of the instant application over a number of claims of the '667 patent, Applicants represent their willingness to file a terminal disclaimer in the instant application to address this rejection as soon as it becomes clear that the Examiner finds the instant application otherwise allowable.

For all of the reasons presented above, it is respectfully submitted that the claims are in condition for allowance in the event Applicants file a terminal disclaimer in the instant application.

No fee is due for the presentation of this amendment. No additional claims have been added and four claims (25-26 and 35-36) have been cancelled. A petition for a three month extension is enclosed as is the fee of \$1020 for the petition. Large entity status applies to the present application. Please charge any additional fee due or credit any overpayment to Deposit Account No. 04-0838.

G25-078.amd3-06

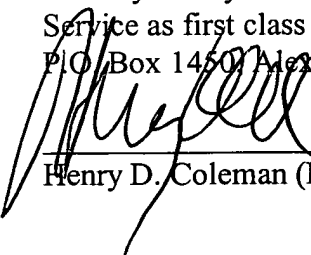
Respectfully submitted,



Henry D. Coleman  
Regis. No. 32,559  
714 Colorado Avenue  
Bridgeport, Connecticut 06605-1601  
(203) 366-3560

#### **Certificate of Mailing**

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia, 22313-1450, dated March 27, 2006.



---

Henry D. Coleman (Reg. No. 32,559)